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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,022	11/26/2001	Holger G. Gassner	07039-171002	1634

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,022

Applicant(s)

GASSNER ET AL.

Examiner

Donna A. Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23 and 32-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claims 23 and 32-43 are pending in this application.

Response to Arguments

Applicant's arguments filed June 21, 2002 have been fully considered but they are not persuasive. The rejection made in paper number 3 over Sanders et al. under 35 U.S.C. 102(b) is maintained and hereby repeated.

Applicant argues that Sanders et al. does not disclose a composition containing combinations of botulinum toxin, a local anesthetic and a local vasoconstrictor. Applicant admits that the above active agents are administered *sequentially* into the nares of a dog. Since the above active agents are administered immediately sequentially, the composition is anticipated and formed in the nares of the dog.

The Examiner is in agreement with the persuasive remarks submitted concerning the outstanding 35 USC 103(a) rejection in paper number 3 over Adams et al. U.S. Patent No. 4,029,794 in view of which the rejection is hereby withdrawn.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 32-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. U.S. Patent No. 5,766,605 A.

Claims 23 and 32-36 are drawn to a composition comprising botulinum toxin, a vasoconstrictor such as epinephrine and a local anesthetic such as lidocaine;

Claims 37-41 are drawn to a composition comprising botulinum toxin, a local anesthetic and optionally a vasoconstrictor such as epinephrine;

Claims 42-43 are drawn to a composition comprising botulinum toxin and a vasoconstrictor.

Sanders et al. teach a composition comprising the decongestant neosynephrine® (phenylephrine, a vasoconstrictor), xylocaine® spray (lidocaine) and type A botulinum toxin. All ingredients were administered to the right and left nasal cavities of anesthetized dogs (column 8, lines 21-36).

1. It does not teach the composition to be mixed in a container.
2. it does not teach the vasoconstrictor epinephrine specifically.

It would have been obvious to mix the ingredients together in a container.

Motivation to do so comes from Sanders et al. teachings that they are useful when mixed together in the nasal cavities of a dog.

2. Regarding the vasoconstrictor phenylephrine of Sanders et al, to substitute the vasoconstrictor epinephrine for the vasoconstrictor phenylephrine would have been

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obvious. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on 6:30 A.M. - 3 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

dj
September 6, 2002

FREDERICK KRASS
PRIMARY EXAMINER
SEP 6 2002
